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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,569	06/25/2001	Maurice M. Moloney	9369-183	8071

7590 05/04/2004

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/887,569	Applicant(s) MOLONEY ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 20, 23-25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 20, 23-25 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 February 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 06 February 2004 has overcome the art rejection over LEDOUX.

Claims 17, 20 and 23-24 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/13993 (UPJOHN), as stated on page 3 of the Office action of 17 December 2002 for claims 17-28, 20 and 23-24.

Claims 17, 20 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al, as stated on pages 4-5 of the Office action of 17 December 2002 for claims 17-18, 20 and 23-25.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/13993 (UPJOHN) in view of Vandekerckhove et al as applied to claims 17, 20 and 23-25 above, and further in view of Orlikowska et al.

The claim is drawn to a safflower seed comprising a fusion protein-encoding gene, wherein said fusion protein comprises somatotropin and wherein said fusion protein accumulates in the seed.

WO 91/13993 (UPJOHN) in view of Vandekerckhove et al teach plant seeds, including seeds of oilseed crops such as cruciferous *Arabidopsis* and rapeseed, which comprise a fusion protein-encoding gene, wherein said fusion protein comprises somatotropin and wherein said fusion protein accumulates in the seed, as discussed previously, but do not explicitly teach transformed safflower seeds. UPJOHN also suggests the use of a variety of dicotyledonous plant species which are cultivated for their seed (see, e.g., page 6, lines 25-31).

Orlikowska et al teach a method for obtaining whole transformed safflower plants (see, e.g., page 85, Abstract; page 90, column 2, middle paragraph), wherein safflower "is a valuable oilseed crop" (see, e.g., page 85, column 1, first sentence of bottom paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of producing fusion proteins comprising somatotropin in a variety of plant species including oilseed species as taught by WO 91/13993 (UPJOHN) in view of Vandekerckhove et al, and to modify that method by incorporating the safflower transformation method of Orlikowska et al to obtain transformed safflower plants which produce somatotropin-containing fusion proteins in their seeds, as suggested by each reference.

No claim is allowed.

Applicant's arguments filed 06 February 2004, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that UPJOHN is not enabled for the production of transformed plants which produce seeds which accumulate somatotropin as a fusion protein, since the reference teaches the cleavage of the signal peptide.

The Examiner maintains that "accumulates" has not been defined with regard to duration of accumulation or the amount of accumulated product. Applicant's mere assertions that UPJOHN is not enabling are not deemed probative. Furthermore, if in fact the accumulation of a somatotropin fusion protein were unpredictable, as urged by Applicant, then Applicant's claims, which are broadly drawn to any fusion protein partner rather than the exemplified oil body protein, contradict Applicant's arguments regarding the enablement of claims broadly drawn to any somatotropin fusion protein partner.

Applicant urges that the obviousness rejection of record is improper, given the failure of UPJOHN to suggest the accumulation of a fusion protein, the lack of a reasonable expectation of success as demonstrated by Bosch et al, and the long-felt need for the claimed invention.

The Examiner maintains that the combination of UPJOHN and Vandekerckhove et al is suggested by each reference, as stated in the Office action of 17 December 2002. The Examiner further maintains that Bosch et al teach success when using a signal sequence which targets the protein product "to a plant compartment where proteins are stably accumulated" (see, e.g., page 3 of the Office action of 12 August 2003, bottom paragraph), such as the seed storage protein sequence taught by Vandekerckhove et al. Furthermore, the claim scope is not commensurate with Applicant's evidence of unexpected results, namely an oil body protein as the fusion

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protein partner. See *Lindner* and *Grasselli* cited previously. Regarding the long-felt need, the Examiner notes that Applicant admits that UPJOHN teaches said need (see, e.g., page 16 of the response of 06 February 2004), thus providing the motivation to combine said reference with Vandekerckhove et al.

Furthermore, it is noted that only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988). Such a reasonable expectation of success has been provided by the cited references, and is not overcome by the unsubstantiated assertions of Applicant, an interested party.

During the personal interview of 03 February 2004, the Examiner suggested that Applicant submit a declaration by a disinterested third party which addresses the alleged non-enablement of UPJOHN, and which also addresses the ability of non-exemplified fusion protein partners to cause the successful accumulation of somatotropin fusion protein in the seeds of transgenic plants. The Examiner awaits such a declaration for consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May 2, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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